

## ENTERAL FORMULATION DESIGNED FOR OPTIMIZED NUTRIENT ABSORPTION AND WOUND HEALING

This is a continuation of application Ser. No. 08/172,857, filed Dec. 23, 1993 now abandoned.

### BACKGROUND OF THE INVENTION

The present invention relates to nutritionally fortified pharmaceutical compositions. More specifically, the present invention relates to compositions for use in intensive care patients.

Intensive care patients describe a broad population of patients who may suffer from a variety of diseases or insults. These patients, however, exhibit some similar requirements. For example, patients suffering from traumatic injury, burns, post-surgery, and some disease states have a significant need for increased nutrients and energy as compared to individuals who are not challenged by such metabolic stress.

Indeed, non-essential nutrients and substances that a body typically can synthesize in adequate supply, may become limiting. Additionally, absorption of nutrients from the gut can be compromised even when there is no direct injury to the gastrointestinal system.

Many intensive care patients are fed either with parenteral formulations or enteral formulations either to replace or supplement a typical diet. For example, in 1991, of an estimated 2.4 million trauma patients in the United States, 13% (310,000) required nutrition support beyond food. Of these patients, 62% of the patients were supported using enteral nutrition, 70% tube-feeding, and 30% oral supplements, while 38% were initially supported using parenteral nutrition and progressed to tube-feeding, if they survived. Similarly, of about 106,000 burn patient admissions in 1991 in the U.S., approximately 20% (21,000) required nutritional support. Of this group, 95% were started on enteral nutrition, 70% began on tube feeding and 30% started on oral supplements.

Numerous enteral formulations have been targeted for trauma and burn patients. These products include: Mead-Johnson's TRAUMACAL®; Sandoz's IMPACT®; Abbott Laboratories' ALITRAQ®; and McGaw's IMMUN-AID®.

Although such products are used in an attempt to treat and/or provide nutritional requirements for such patients, the inventors of the present invention do not believe that these products meet the needs of such patients.

Accordingly, there is a need for an enteral nutritional formulation which meets the nutrient requirements of intensive care patients who may have altered nutritional requirements and compromised absorptive capacity.

### SUMMARY OF THE INVENTION

The present invention provides an enteral nutritional formulation that meets the nutrient requirements of intensive care patients who may have compromised absorption capacity. The present invention meets the unique nutrient needs of the patient that are generated due to tissue repair and healing requirements.

To this end, in an embodiment the present invention provides a method for treating and/or providing nutritional support to intensive care patients comprising the steps of administering a therapeutically effective amount of a composition comprising: a protein source; a carbohydrate source; and a lipid source including a source of medium chain triglycerides (MCTs), a source of omega-3 fatty acids,

and a source of omega-6 fatty acids. In an embodiment, the source of omega-3 fatty acids comprises at least 2.3% of the total calories.

In an embodiment, a method for treating and/or providing nutritional support to an intensive care patient is provided comprising administering a therapeutically effective amount of a composition comprising: a high protein content of at least 22% of the total calories; a carbohydrate source; and a high lipid content of at least 30% of the total calories.

In an embodiment, a method for treating an intensive care patient is provided comprising administering a therapeutically effective amount of a composition comprising: 22-28% of the calories as a protein; 33-45% of the calories as a lipid, the lipid provides at least 40% of its caloric content as medium chain triglycerides, and further including an omega-3 fatty acid source and an omega-6 fatty acid source; and a carbohydrate source. Preferably, the caloric density of the composition is at least 1.3 Kcal/ml.

If desired the composition can include sources of: glutamine; arginine; proline; and/or cysteine.

It is an advantage of the present invention that it provides an enteral nutritional formulation that is designed to optimize nutrient absorption and wound healing in trauma patients.

Moreover, an advantage of the present invention is to provide a composition having a high protein content, a high lipid content, and a high caloric density to meet protein and energy needs.

Furthermore, an advantage of the present invention is to provide a composition that has reduced water and carbohydrate content reducing the risk of diarrhea due to carbohydrate intolerance, hyperglycemia, over hydration, and the like.

Still further, an advantage of the present invention is that nutrient malabsorption is reduced by the absence of whole proteins and by the use of protein hydrolysate, free amino acids and medium chain triglycerides in the enteral formulation of the present invention.

Additionally, an advantage of the present invention is that it is a ready-to-use formulation, and not a powder that requires mixing before use, reducing the risk of bacterial contamination during the mixing process.

Moreover, pursuant to the present invention, healing and tissue repair/cell division is promoted by the use of certain components.

It is also an advantage of the present invention that inflammatory reactions are minimized.

Additional features and advantages of the present invention are described in, and will be apparent from, the detailed description of the presently preferred embodiments.

### DETAILED DESCRIPTION OF THE PRESENTLY PREFERRED EMBODIMENTS

The present invention provides enteral formulations specifically designed for use with intensive care patients, specifically, trauma, burn, and post-surgery patients. Moreover, the present invention provides methods of treating such patients.

Pursuant to the present invention, an enteral formulation is provided that is designed to optimize nutrient absorption and wound healing in trauma patients. The enteral formulation of the present invention meets the nutrient requirements of such patients with compromised absorptive capacity. The formulation also meets nutrient needs unique to tissue repair and healing of the patients.